



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2017-F-4511]

Food Additives Permitted in Feed and Drinking Water of Animals; Gamma-Linolenic Acid
Safflower Oil

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of gamma-linolenic acid safflower oil (GLA safflower oil) as a source of omega-6 fatty acids in dry food for adult cats in the maintenance life stage. This action is in response to a food additive petition filed by Arcadia Biosciences, Inc.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. See section V of this document for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept

comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting objections. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on <https://www.regulations.gov>.
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville,

MD 20852.

- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-F-4511 for "Food Additives Permitted in Feed and Drinking Water of Animals; Gamma-Linolenic Acid Safflower Oil." Received objections, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies in total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of objections. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your objections and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other

applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper objections received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carissa Doody, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV-228), Rockville, MD 20855, 240-402-6283, carissa.doody@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the *Federal Register* of September 14, 2017 (82 FR 43197), FDA announced that we had filed a food additive petition (animal use) (FAP 2302) submitted by Arcadia Biosciences, Inc., 202 Cousteau Pl., Suite 200, Davis, CA 95618. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of GLA safflower oil as a source of omega-6 fatty acids in dry food for adult cats in the maintenance life stage.

The petition for the safe use of GLA safflower oil as a source of omega-6 fatty acids in dry food for adult cats in the maintenance life stage (FAP 2302) indicated that the concentration of gamma-linolenic acid was between 350 and 450 milligrams (mg) gamma-linolenic acid per gram of the additive or the safflower oil blend. A previous petition (FAP 2275) that provided for

the safe use of GLA safflower oil as a source of omega-6 fatty acids in dry food for adult dogs in the maintenance life stage indicated that the concentration of gamma-linolenic acid was between 400 and 450 mg gamma-linolenic acid per gram of the additive or the safflower oil blend (82 FR 38595, August 15, 2017).

In amending § 573.492 (21 CFR 573.492) to allow for the safe use of GLA safflower oil in dry food for adult cats, the current allowable concentration range for gamma-linolenic acid in the additive or the safflower oil blend was amended to incorporate the broader range supported by FAP 2302. This does not adversely alter the technical effect from use of the additive in adult maintenance dog food because provisions in the August 15, 2017, rule (82 FR 38597), revised in paragraph (b)(2) of this rule, specify that adjustments must be made for differing concentrations of gamma-linolenic acid to meet other specified parameters.

II. Conclusion

FDA concludes that the data establish the safety and utility of GLA safflower oil as a source of omega-6 fatty acids in dry food for adult cats in the maintenance life stage and that the food additive regulations should be amended as set forth in this document. This is not a significant regulatory action subject to Executive Order 12866.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure.

IV. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Dockets Management Staff (see ADDRESSES) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573--FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Revise § 573.492 to read as follows:

§ 573.492 Gamma-linolenic acid safflower oil.

The food additive, gamma-linolenic acid safflower oil, may be safely used in animal food as a source of gamma-linolenic acid and other omega-6 fatty acids in accordance with the following conditions:

(a) The additive is the oil obtained from whole seeds and/or partially dehulled seeds of a *Carthamus tinctorius* L. safflower Centennial variety genetically engineered to express the delta-6-desaturase gene from *Saprolegnia diclina* Humphrey. The 453 amino acid, delta-6-desaturase enzyme converts the fatty acid linoleic acid to gamma-linolenic acid (all-*cis*-6,9,12-octadecatrienoic acid) during seed development.

(1) The additive obtained from the seeds of the genetically engineered safflower Centennial variety may be blended with oil obtained from seeds of non-engineered oleic acid safflower varieties in order to meet the specifications required for the additive or the blend in paragraph (a)(2) of this section.

(2) The additive or a safflower oil blend containing the additive for use in animal food meets the following specifications:

(i) Crude fat content of the additive or the safflower oil blend is not less than 99.5 percent.

(ii) Gamma-linolenic acid content is between 350 and 450 milligrams (mg) gamma-linolenic acid per gram of the additive or the safflower oil blend.

(iii) Total content of stearidonic acid and *cis, cis*-6,9-octadecadienoic acid in the additive or the safflower oil blend must not exceed a total of 0.3 percent.

(b) Addition of the additive, or the safflower oil blend, to complete dry adult maintenance

dog food must meet the following:

(1) Addition of the additive or the safflower oil blend cannot provide more than 36 mg gamma-linolenic acid per kilogram body weight of the dog per day in more than 86 mg of the additive or the safflower oil blend. This maximum addition rate of the additive, or the safflower oil blend, is 0.3 percent of a complete dry adult maintenance dog food containing 3,600 kilocalories of metabolizable energy per kilogram of food as-fed.

(2) Adjustments must be made for differing concentrations of gamma-linolenic acid and for dog food formulas of different caloric density and/or that are fed to specific weights, breeds, or dogs of different activity levels to meet the requirements of this paragraph.

(c) Addition of the additive, or the safflower oil blend, to complete dry adult maintenance cat food must meet the following:

(1) Addition of the additive or the safflower oil blend cannot provide more than 33 mg gamma-linolenic acid per kilogram body weight of the cat per day in more than 79 mg of the additive or the safflower oil blend. This maximum addition rate of the additive, or the safflower oil blend, is 0.5 percent of a complete dry adult maintenance cat food containing 4,000 kilocalories of metabolizable energy per kilogram of food as-fed.

(2) Adjustments must be made for differing concentrations of gamma-linolenic acid and for cat food formulas of different caloric density and/or that are fed to specific weights, breeds, or cats of different activity levels to meet the requirements of this paragraph.

(d) To assure safe use of the additive, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of the additive shall bear the following:

(1) The name of the additive, gamma-linolenic acid safflower oil, or GLA safflower oil;

(2) A guarantee for the minimum content of gamma-linolenic acid; and

(3) Adequate directions for use such that the finished animal food complies with the provisions of paragraphs (b) and (c) of this section.

Dated: February 22, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-03514 Filed: 2/27/2019 8:45 am; Publication Date: 2/28/2019]